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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,461	01/18/2005	Javier Bartoli Orpi	3494-106	2242

6449 7590 09/21/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
09/21/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/521,461	BARTOLI ORPI ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-11,14-18,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11,14-18,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *18 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-11, 14-24 are pending in this application.

Claims 19-22 are drawn to non-elected inventions.

Claims 12-13 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 14-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification lacks adequate support for the claims. The terms "solvate" and "prodrug" are not defined in the specification so as to ascertain the structures of the compounds included and/or excluded by the terms.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-11, 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "solvate" and "prodrug" are not defined in the claims so as to ascertain the structures of the compounds included and/or excluded by the terms, and the metes and bounds of the claims. Therefore, the claims are indefinite.

Claims 15-18 are drawn to composition comprising one or more additional drugs or chemotherapeutic agents. It is not possible for the composition to comprise any drug or chemotherapeutic agent without relevance to the disease being treated. Since, the instant compounds cannot treat all known diseases, the composition must comprise additional drug that would work in synergy with the instant compounds. By replacing the drugs or agents with specific and relevant drugs the rejection would be overcome.

Claims 17-18 are confusing and therefore indefinite. The claims are drawn to a product (composition) comprising one or more additional drug or chemotherapeutic agent as "a combined preparation for simultaneous, sequential or separate" administration. Sequential or separate administration implies the drugs are not combined together in the same composition, which is contrary to the phrase "a combined preparation". It is not possible for the drugs to be combined and separate at the same time. Also, the claims are drawn to the composition of the same compounds as in 15-16, and therefore are substantial duplicates of 15-16. Under the US patent practice the two sets of claims cannot be in the same application. By deleting claims 17-18 the rejection would be overcome.

The acids of the instant compounds are being claimed in claims 1, 10 and again in claims 23-24. Claims 1, 10 are drawn to the acids, the solvates or the prodrugs while claims 23-24 are drawn to the acids the second time. By deleting claims 23-24 the rejection would be overcome.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 14-18, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Arnolds-Stanton et al., J. Org. Chem. (1991), Vol. 56(1), pp. 151-157.

Arnolds-Stanton et al., disclose compound 13 obtained in a mixture with similar drugs (others). See page 153, column 1, line 6 to the end of the paragraph. The compound anticipates the instant compounds and their compositions in claims 1-5, 7-9, 14-18, 23 and the prodrugs and compositions of the instant compounds in claims 1-11, 14-18, 23-24.

Claims 1-11, 14-18, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Carson et al., US 5,374,772.

Carson et al., disclose the compounds in column 2, lines 35-50, and compositions comprising them. See page column 1, lines 38-40. The compounds anticipate the prodrugs of the instant compounds and their compositions in claims 1-11, 14-18, 23-24.

Claims 1-11, 14,17, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Mu et al., Colloids and Surfaces A: Physiochem. Eng. Aspects (2001), Vol. 181, pp. 303-313.

Mu et al., disclose ethyl 2,4-dihydroxybenzoate obtained by Williamson synthesis and used in a mixture with similar compounds. See scheme 1, beginning of paragraphs 3-5 of *2.1. Materials*, page 305. The compound anticipates the instant compounds and their compositions in claims 1-2, 8-9, 14, 17, 23 and the prodrugs and compositions of the instant compounds in claims 1-11, 14, 17, 23-24.

Claims 1-11, 14-18, 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Hardcastle et al., Tetrahed. Letters, (2001), Vol. 42, pp. 1363-1365.

Hardcastle et al., disclose compound 1g obtained in a mixture with similar drugs. See page 1364, column 1, last paragraph and first paragraph of column 2. The compound

anticipates the instant compounds and their compositions in claims 1-5, 7-9, 14-17, 23, and the prodrugs and compositions of the instant compounds in claims 1-11, 14-18, 23-24.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11, 14-18, 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnolds-Stanton et al., J. Org. Chem. (1991), Vol. 56(1), pp. 151-157, Mu et al., Colloids and Surfaces A: Physiochem. Eng. Aspects (2001), Vol. 181, pp. 303-313, Hardcastle et al., Tetrahed. Letters, (2001), Vol. 42, pp. 1363-1365, individually.

Applicant claims compounds of formula I and compositions thereof. In preferred embodiments, the compositions comprises additional drug

Determination of the scope and content of the prior art (MPEP 2141.01)

Arnolds-Stanton et al., disclose compound 13 obtained in a mixture with similar drugs (others). See page 153, column 1, line 6 to the end of the paragraph.

Mu et al., disclose ethyl 2,4-dihydroxybenzoate obtained by Williamson synthesis and used in a mixture with similar compounds. See scheme 1, beginning of paragraphs 3-5 of *2.1. Materials*, page 305.

Hardcastle et al., disclose compound 1g obtained in a mixture with similar drugs. See page 1364, column 1, last paragraph and first paragraph of column 2.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the instant invention and that of Arnolds-Stanton et al., is the length of the carbon chains at positions R1 and R3. In other words, applicant replaced H with alkyl or vice versa.

The difference between the instant invention and that of Mu et al., is the length of the carbon chain at position R1. In other words, applicant replaced H with alkyl or vice versa.

The difference between the instant invention and that of Hardcastle et al., is the length of the carbon chain at position R3. In other words, applicant replaced H with alkyl or vice versa.

Finding of prima facie obviousness---rational and motivation (MPEP 2142.2413)

However, H and alkyl are art recognized equivalents. *In re Lincoln*, 53 USPQ 40 (CCPA, 1942); *In re Druey*, 319 F.2d 237, 138 USPQ 39 (CCPA, 1963); *In re Lohr*, 317 F.2d 388, 137 USPQ 548 (CCPA, 1963); *In re Hoehsema*, 399 F.2d 269, 158 USPQ 598 (CCPA, 1968); *In re Wood*, 582 F.2d 638, 199 USPQ 137 (CCPA, 1978); *In re Hoke*, 560 F.2d 436, 195 USPQ 148 (CCPA, 1977); *Ex parte Fauque*, 121 USPQ 425 (POBA, 1954); *Ex parte Henkel*, 130 USPQ 474, (POBA, 1960). When the difference between compounds is the length of a carbon chain such are adjacent homologs. However, adjacent homologs are prima facie obvious. *In re Henze*, 85 USPQ 261 (1950).

Therefore, the instant invention is prima facie obvious from the teachings of Arnolds-Stanton et al., Mu et al., and Hardcastle et al. One of ordinary skill in the art would have known to replace H with alkyl, or vice versa, at the time the instant invention was made. The motivation is from knowing that H and alkyl are equivalents.

Specification

The specification does not have Brief Summary of Invention, Brief Description of Drawings and Detail Summary of the Invention.

Priority Document

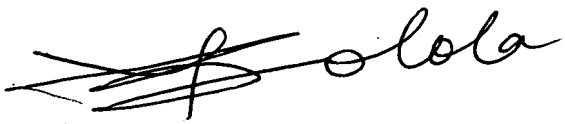
This application claims priority of a foreign document. However, certified English translation of the foreign document is not on file.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



TAOFIQ SOLOLA
PRIMARY EXAMINER

Group 1625

September 8, 2007